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Recent Trends on Microsponges: Opportunities and Challenges

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ABSTRACT

Microsponges are a recent innovative technology for target-specific delivery systems with controlled release. Microsponges are made up of tiny, pliable beads that are filled with an active ingredient and range in size from 10 to 25 microns. Microsponges offer several advantages, making them a flexible drug delivery mechanism. They are also very dependable, steady, not scratchy, not harmful, not irritated, and not carcinogenic, with fewer implications and improved complying patients. Microsponges delivery system (MDS) has recently received attention for the regulated delivery of medications on the skin's surface with the reassurance that the medication will remain mostly localized and won't into the bloodstream in huge amounts. MDS has a bright future in the pharmaceutical industry thanks to its special qualities like a tiny size, good carrier properties, increased performance of the product and quality, advanced release, less discomfort, and excellent thermal, physical, and chemical properties that give them the flexibility to develop novel product forms.

INTRODUCTION [1],[2],[3],[4],[5]

As medication delivery technology advances, a wide variety of pharmacological classes are being created every day. A new medication release system with calculated predefined ratios at various points of function must be advanced for a drug to be successful debt any condition.[1] The majority of traditional dosage forms, such as tablets, capsules, creams, lotions, and gels with rapid release, are crude and have several drawbacks, including low bioavailability, skin and stomach irritation, unpleasant reactions, and harmful effects of the active ingredients.[2] Highly cross-linked, polymeric permeable microspheres with numerous interrelated gaps make up microsponges, which are also made of collapsible structures that are filled with an active medicinal ingredient. The porous surface of microsponges allows a variety of active medicinal ingredients to be held in and released at the special absorption site in a diversity of quantities. Depending on the size of the pores, the microsponges continuous pattern of open pores allows the medicine to be trapped inside to diffuse outward at a controlled rate.[3]

A regulated release of the active component is present in this microsponge formulation. Small, inactive sphere formulations that don't annoy the skin film are used in microsponge medication administration. These formulations were formed to effectively deliver the medicinal ingredients at the administration site while using the smallest quantity of medication.[4] Microsponges were created by Richard Won scientist. The range of the bead's diameter is 5-100 m. The average human sin is 5 microns in size. The enduring spheres cannot penetrate the skin. The skin gradually absorbs the active ingredients that are surrounded by the pores. The microsponges' capacity to form cages is due to the polymers applied in their manufacture. The polymers E- RS100, E- RS PO, E-S100, polyhydroxy butyrate, and polyvinyl benzene are the most commonly utilized for production.[5]

History of Microsponges [6]

Won created the microsponge expertise in 1987, and innovative polymer structures, Inc. received novel patents. This corporation formed a lot of dissimilar techniques and used them for enhancing over-the-counter, and doctor-prescribed products.

Characteristics [7],[8]

1. Work well with a variety of materials and vehicles.

2. Microsponges are identically active at tricking units.

3. Microsponges are judged based on their ability to drift freely.

4. They persist stably between pH 1 and 11.

5. They are thermostable, these formulations can endure temperatures of up to 130 °C.

Advantage [9],[10],[11]

1. MDDS breaks the active component from building up in the dermis and epidermis.

2. By recalling their efficacy, MDDS declines the irritation of active drugs.

3. It is extended-release and has a continuous activity aimed at up to 12 hours.

4. Without drying, microsponges can engage up to six times their weight in oil.

5. Increases stability, thermal, physical, and chemical durability.

6. Enables the insertion of immiscible products.

The Advantage of microsponges over additional formulations [1]

Microsponges offer the medication's extended and sustained release. Lowering irritability rises patient compliance. Microsponges are physical, chemical, and thermally stable ingredients in formulations. By engrossing them, they make the skin feel less slimy and oily.

The advantage over the conventional formulation [3]

The exterior layers of the skin are often the mark of topical medication structures. Upon application, these goods disperse their active components. They carry a concentrated covering of the active substance, which is eagerly engrossed. This causes a collection of active chemicals to figure up in the epidermis and dermis. As shown by MDS benzoyl peroxide formulations, which have good properties with negligible irritability, a microsponge system can substantially minimize a drug's adverse effects, such as irritability, without negotiating its effectiveness.

Advantage over ointments [1], [11]

Because of their poor penetration proficiency, ointments require high attention from active agents for the required efficient therapeutic action. High doses induce unpleasant side effects,

such as itchiness and allergic reactions, and are regularly unpleasant and sticky, which makes patients less prospective to comply. when a microsponge system increases the amount of period a vigorous constituent is current on the coating's external or with the epidermis while reducing its transcutaneous access into the body.

Marketed product of microsponges [12]

Before they may be used for verbal drug delivery systems, a variability of microsponges-based products that are sold for topical use need to undergo thorough research and scale-up contests at pilot plants. marketed goods that include microsponges of the active ingredient to be listed.

Marketed preparation based on microsponges drug transport structure

Manufacture	Drug	Brand Name
Dermic Labs, Inc, US	5- FU	Carac™
A.P. Pharma Inc, US	Tretinoin	Retin – A Micro®
Polymer system , US	Melanin	Melanin Microsponge®
Skin Media, US	BPO	NeoBenz®
Avon, New York	Retinol	Line Eliminator Double Vitamin A1 Makeover Action
Biomedical	Retinol	Retinol Cream
Sothys , Paris , France	Retinol	Retinol 15 NightCream
Skin Medica, Inc, New York, US	Hydroquinone and Retinol	EpiQuin Micro
Embil Pharmaceutical Co. Lttd. Istanbul Turkey		Sportscream RS and XS
Scott Paper Co. Pennsylvania, US	Dimethicone	Ultra Guard
SDR Pharmaceuticals, Inc, Andover, NJ, US	Ammonium lactate	Lactrex™ 12% Moisturising Cream

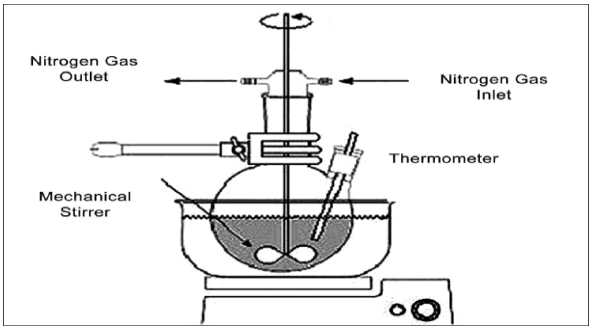
Preparation of Microsponges

Depending on the physical and chemical features of the medication to be loaded, drug filling in microsponges can be accomplished in many steps, as detailed in the "liquid-liquid suspension polymerization" and "quasi emulsion solvent diffusion" procedures.

Liquid – Liquid Suspension Polymerization [10], [11]

In this "liquid-liquid suspension polymerization" method, spongy microspheres are made using the liquid-liquid suspension polymerization method. When making them, the monomerous are first decomposed with the active agent in an appropriate monomer solvent solution before being discrete in the aquatic phase, which is finished up of additives. Then the catalyst is added, the temperature is raised, or irradiation is used to start the polymerization. The several stages in the research of microsponges are brief:

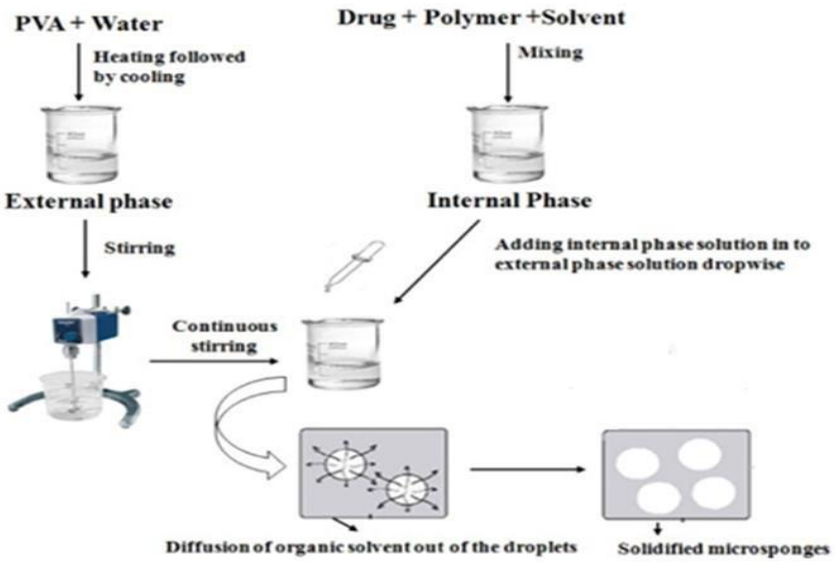
1. Selection of monomers or a monomer mixture.
2. Creation of cable monomerous as polymerization begins.
3. Ladders formation as an effect of cross-connecting among chain monomerous.
4. The monomerous ladder is collapsible to create sphere-shaped units.
5. The collection of microspheres, which springs increases the development of lots of microspheres.
6. Obligatory groups to form microsponges.



Liquid suspension polymerization

Quasi Emulsion Solvent Diffusion [5]

Drugs, volatile Solvents, polymers, and TEC made up the internal phase. TEC was additional at a rate of 20% of the polymer to help with flexibility. An exterior phase inclusive of distilled water and PVA. Primarily, the interior phase was ready and added to the exterior phase at ambient temperature. The combination was nonstop blown for the following 2 hours after emulsification. Then the tincture was sieved to distinguish the microsponges. The product was cleaned and dried out for 12 hours at 40 °C in an air oven.



Multiple Emulsion Solvent Diffusion [13]

To make porous, biodegradable microspheres, a method was formed. With the accumulation of stearyl amine, an aqueous internal phase was utilized, and the span was dispersed in solution. To create a (w/o/w) dual emulsion, this w/o cream is then spread once again with polyvinyl alcohol in an aqueous phase. Using this method discloses the benefit of sanctioning both soluble and insoluble actives. Additionally, thermolabile substances like protein may be captured using this technique.

Lyophilization Technique [14]

In this situation, microspheres are made via the gelation procedure. This microsphere can be transformed into permeable microsponges through the process of lyophilization. In this trial, microspheres were lyophilized and incubated. The incubation process used a chitosan hydrochloride solution. Microsponges with pores are produced once the solvent is removed during lyophilization.

Optimum parameters for the formulation of microsponges [9]

Sr. NO.	Optimum value	Specification
i.	1:1 ,1:2 ,1:3 ,2:1 , 3:1	Drug-to-Polymer Ratio
ii.	100 -300	Dosage of the medication (mg)
iii.	100	PVA (mg)
iv.	Ethyl alcohol	Solvent for the inner phase (ml)
v.	10	Quantity of interior phase solvent
vi.	100	Quantity of water in the exterior phase (ml)
vii.	25℃	The temperature of the interior phase
viii.	Magnetic stirrer and bath sonicator	Types of method
ix.	100rpm	Magnetic stirrer speed

Mechanism of Drug Release [15],[16],[17],[18]

In reaction to a variety of outside stimuli, microsponges can be programmed to produce a specific amount of active substances over a while.

1. pH Triggered System

You can change the covering on the microsponge to start the pH-based release of the active. This has several uses for drug delivery.

2. Temperature Release

Temperature is one factor that can act in the release of active materials from microsponges. At room temperature, some of the compounds retained inside the Microsponge, like emollients and sunscreens, maybe too viscid to naturally distribute onto the skin. Their

viscosity may drop as an outcome of being warmed by the body's warmth, the sun, or another heat source, increasing the flow rate.

3. Pressure Release

When pressed or squeezed, the microsponges system releases liquid or active components, refilling the skin's supply of the substance that has been trapped there. The sponges' capability to release water and the resilience of the microsponges could also affect how much is released.

4. Solubility

In the occurrence of water, microsponges comprising water-soluble compounds such as sterilizers and deodorants will release the substance. Diffusion, while taking into account the ingredient's partition coefficient among the micro sponges and the external system, can also initiate the release.

Characterization of microsponges [19]

The physiochemical depiction of microsponges is a vibrant phase in the positive strategy and construction of these adaptable microcarriers. In accumulation to (UV) and (HPLC), this transfer system needs many corresponding methods like FTIR, DSC, PXRD, SEM, and permeability studies for inspecting their physical and morphologic features**.**

1. Fourier Transform Infrared Spectroscopy [20]

The formulations of pure drugs, polymers, drug-polymer physical combinations, and micro sponges are all subjected to Fourier transform infrared spectroscopy (FTIR). The materials are put into potassium bromide discs, and the FTIR mass spectrometer examines them. To show that no chemical interactions or deviations occurred during the manufacture of the formulations, the peaks in the spectra of the microsponges should still correspond to the drug's distinctive bands.

2. Differential Scanning Colorimetry [21]

A study using differential scanning calorimetry (DSC) was conducted to assess the drug's thermal performance and thermotropic properties. A thermogram (Mettler-Toledo DSC 821e Switzerland) was obtained after a sample of about 5 mg was sealed in an aluminum pan and fiery at a rate of 10 °C/min during a temperature range of (40-200) °C.

3. Scanning Electron Microscopy [22]

"SEM" was used to examine the particle's shape and surface properties. In a vacuum, the samples were layered with palladium alloy. Layered samples were then examined using microscopy on a JEOL-JSM, 6100, Japan, in a vacuum at room temperature. Using NEM TAPE adhesive paper, the dry samples were mounted before being photographed.

4. Dissolution Studies [23]

A dissolution tool for investigating the dissolution profile of the loaded microsponges, USP with certain alterations was utilized. To ensure sink conditions, the solubility of the medicine is taken into account when selecting the dissolution media. Samples were taken out of the dissolution liquid at many time intervals and subjected to a suitable analytical method. Then, to measure the kinetics of drug release from the formed microsponges, kinetics studies were conducted by suitable the in vitro drug release information into numerous models.

5. Particle size analysis [24]

Optical microscopy, laser light diffractometry, and other appropriate methods are used to measure the microsponge's particle sizes. observed that the gel microsponge was uniform in size consuming an optical microscope to evaluate the particle size. In the evaluation of the typical particle size of 110.30 m, the pore size was less than 1 m. The microsponge was observed using optical microscopy, and the particle size under from 48 to 65.2 m, with a mean particle size of 58.37 0.52 m. discovered that the mean pore size was 8.310.38 m and that the pores were spherical.

6. Compatibility studies [25]

(TLC) and (FTIR) can be used to consider a drug's compatibility with reaction adjuncts (FT-IR). The influence of polymerization on the crystallinity of the medication can be inspected by (XRD) and (DSC). For DSC, samples can be precisely weighed into pans, sealed, and burned at a rate of 150°C per minute during a temperature range of 25–430°C in a nitrogen atmosphere.

7. Pore Structure [26]

Microsponge's porosity properties are critical for stalking the duration and strength of the effects of active ingredients. Average pore sizes, forms, and geomorphology of the holes can

be measured by employing the mercury interruption porosimetry technique. Using the same process, it is probable to observe how hole thickness and dimensions affect the percentage of drug release from microsponges.

8. Resiliency [27]

This determines the viscoelastic nature of the formula (MS). The study's outcome is dependent on how firm the final formulation is. Increased cross-linking may cause the rate of medication release to slow down. If there is no indication of a disturbance even after squeezing the tablet, this test is considered to be resilient.

9. Determination of true density [28]

With an ultra-pycnometer and helium fume, the real compactness of microparticles is judged, and the result is determined by averaging out some measurements**.**

10. Polymer Monomer Composition [29]

The drug release from microspheres is administered by elements such as drug loading, polymer structure, and microsphere size. The MDS's polymer composition can affect the entangled drug's partition coefficient among the vehicle as well as the microsponge system, directly affecting how rapidly the drug is released. Plotting cumulative% medication release vs time allows for the study of drug release from microsponge systems with several polymer compositions.

Limitation of microsponges [30]

1. Toxic effects in the body could result from beneficial minute amounts of leftover monomers.

2. Since organic solvents are regularly used in the preparation processes as porogen some of which may be highly flammable they present a safety risk as well as an environmental risk.

Applications [31]

Sr. No.	Active agent	Application
i.	Suntan lotion	Long-term efficacy of the item with enhanced safety against blisters and sun-related problems at high concentrations, as well as lower irritability and adaptation.
ii.	Anti- Acne	Maintaining efficacy while reducing skin irritability and sensitivity.
iii.	Anti- Fungals	Actives are released continuously.
iv.	Anti-Inflammatory e.g. hydrocortisone	Long-lasting action that reduces skin allergies and skin eruptions
v.	Anti-dandruff e.x. zinc pyre-thione	unpleasant scent Reduced, decreased discomfort, and increased safety and efficacy
vi.	Antipruritics	Extend and enhanced activity
vii.	Rubefacients	Extensive activity with concentrated irritancy, oiliness, and smell
iii.	Skin depigmenting agents e.x. Hydroquinone	Enhanced equilibrium against corrosion with higher efficiency and aesthetic request

Biomedical applications of microsponges

For Topical Administration [32]

A solitary microsponge particle has a size of less than one-thousandth of an inch, making it similar to talcum powder or other tremendously small particles. Additionally, the non-collapsible structure of these sponges has a multitude of interrelated gaps that can accommodate a variety of pharmacological compounds. A typical microsponge has a porous outer surface, agreeing with drug molecules to enter and exit the sphere. Inert polymers are

used to make microsponges. Despite being small, their massive systems prevent them from passing over the stratum corneum of the skin when applied topically. Skin irritability is a mutual side consequence of the topical acne treatment drug benzyl peroxide.

Bone Substitute in Bone and Tissue Engineering [33]

Complexes were formed by a mixture of calcium-deficient hydroxyapatite powder and tricalcium phosphate grains with pre-polymerized polymethyl methacrylate powder and liquid methyl methacrylate monomer. The resulting complexes had a porous appearance and performed as microsponges. When the sponge sheet of collagen was integrated into the subcutis of the mouse, the basic fibroblast development factor was maintained release and verified spatial angiogenic movement in a dose-dependent way, based on the biodegradation of the sponge's matrix. These point to the importance and therapeutic value of form 1 collagen as a source of bFgF.

Recent Advances [34],[35],[36],[37],[38]

The development of cyclodextrin (CD)-based nano-sponges for drug delivery is one example of how technology has been innovative through the variety of techniques used to make nanosponges and porous tiny pellets. Many medications, including dexamethasone, flurbiprofen, antimicrobial drug coordination compound, itraconazole, and others, are administered orally using these sophisticated drug delivery systems. By treating this -CD molecule with biphenyl carbonate, it is cross-linked, ensuing in the development of nanosponges. The use of a cytotoxic substance as a carrier system within the formulation has been found to increase the drug's effectiveness and is frequently used to target cancer cells as well as to deliver gases, according to research.

Sr.No.	Research Paper Information	Research Work
1.	The microsponge-based gel is a simple and valuable plan for formulating and releasing Tazarotene in an exact manner [Khattab A et. al. 2022]	Tazarotene (TZR) was given as a microsponge-based gel in a regulated manner to lessen side effects. It follows the same methodology as a study the authors of the article conducted on the medication Clindamycin. Emulsion solvent diffusion is the methodology

		employed in both types of research. To create four different formulations of TZR microsponges, we changed the concentrations of the polymer and emulsifier. In addition, we created two more microsponge formulations using two different emulsifiers and two different solvents. Next, we looked at the physical characteristics of each formulation and the interactions between drugs and polymers. We discovered that the microsponge formulations indicated by T1 and T3 had higher manufacturing yield and entrapment efficiency, and their unit size was appropriate, confirming findings from our prior investigation of clindamycin.
2.	Formulation and Characterization of Luliconazole Microsponges Loaded Gel for Topical Delivery [Farhana Sultan et.al. 2021]	The luliconazole microsponges were ready by 2 step process known as the quasi-emulsion solvent diffusion method. In this, EC and E RS 100 polymers along with different drug: polymer ratios are used. The two-step procedure, known as the internal phase, entails the dissolution of the polymer in dichloromethane as the solvent, followed by the addition of the medication and PEG 400 under ultrasonication at 350°C. The exterior phase, which was made by dissolving PVA in distilled water, was next prepared, and after being put dropwise into it, the inner phase was continually swirled for two hours to create the microsponge. The

		prepared microsponge was filtered apart, cleaned up, and desiccated in a hot air oven for 24 hours at 400C. To determine production yield, the micro sponges are then weighed.
3.	Formulation Advancement and In Vitro Release Studies of Tenofovir-containing Microsponges [Ravinder Naik Eslavath et .al. 2019]	TNF-containing microsponges were created using the "Quasi emulsion diffusion method". Glycerol and dibutyl phthalates were utilized as plasticizers, and eudragit L-100 was used as a polymer. Five formulations (F1-F5) of the drug and polymer were tested in various ratios, including 1:1, 1:2, 1:3, 1:4, and 1:5. Physical characteristics such as size, crystallinity, and interactions were used to characterize them.
4.	Design and characterization of curcumin microsponges for topical drug delivery [Meenakshi Bhatia et . al. 2018]	The "quasi-emulsion solvent diffusion" approach was used to create curcumin (CUR) microsponges. In the internal phase, dichloromethane was mixed with ethyl cellulose (2% w/v). With persistent stirring at 600 rpm, the medication (100–500 mg) was slowly added to the EC solution. The aquatic exterior phase containing PVA (0.5% w/v) was then dropped by drop into the internal phase. The microsponges were created by the system's dichloromethane evaporating after two hours of churning. The microsponges were sieved, dry in a oven at 40 °C until their weight was consistent, and then placed in an airtight vessel for storage.

Future Prospects [39]

The most recent front-line technology, microsponge, was primarily created for topical delivery systems. The development of novel product forms is flexible thanks to the microsponge drug delivery system's special abilities, which include better physical, chemical, and thermal stability, longer release, better drug release profile, compact irritation, and enhanced product performance and elegance. Future microsponge carrier systems have a purpose in the cosmetics industry. Due to the formulation's flexibility, these can be used in a variety of applications and a new route for drug delivery systems.

1. In vivo study
2. Studies on stability
3. Pharmacokinetics in living organisms

Safety Aspects [40]

Microsponge safety evaluations can be conducted by:

1. Rabbit eye exasperation research.
2. Rabbit skin impatience research.
3. Bacteria mutagenicity.
4. Rat study on oral toxicity.
5. Guinea pig allergenicity.

CONCLUSION

The majority of research is being done to exploit the use of cost and therapy efficacy in the highly competitive and fast-evolving field of microsponge drug delivery systems. Since microsponge delivery systems offer excellent qualities including elegance and superior product performance, they have a bright future in different pharmaceutical applications in the years to come. The use of microsponges in the topical delivery system can be valuable for oral medication delivery using biodegradable polymers and for dosage form maintenance on the skin. When other stimuli are present, Microsponge also releases its actives on a timer. The microsponge delivery system is a new subject that needs to be respected in the upcoming years with more research studies.

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